DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-154/S-036
NDA 20-155/S-027
NDA 20-156/S-028

Bristol-Myers Squibb Company
Attention: Mari-Laure Papi
Associate, Worldwide Regulatory Affairs
5 Research Parkway
Wallingford, CT 06492

16 NOV 2001

Dear Ms. Papi:

Please refer to your supplemental new drug applications dated January 4, 2001, received January 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® (didanosine) Buffered Tablets, VIDEX® (didanosine) Buffered Powder for Oral Solution, and VIDEX® (didanosine) Pediatric Powder.

We acknowledge receipt of your submissions dated February 6, 2001, October 22, 2001, October 23, 2001, and November 8, 2001.

These "Changes Being Effected" supplemental new drug applications provide for the inclusion of new information regarding fatal lactic acidosis in pregnant women, to be included in the Boxed Warning, Warnings, and Precautions section of all VIDEX® (didanosine) labels. Additionally, these supplemental applications provide for the inclusion of wording outlining the potential for redistribution/accumulation of body fat concurrent with the use of nucleoside analogues in the Precautions, Precautions/Information for Patients, Adverse Reactions, and Patient Information sections of all VIDEX® (didanosine) labels.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 22, 2001, patient package insert submitted October 22, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Destry M. Sillivan, M.S., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Debra Birnkrant, M.D.,
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research